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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,093	06/18/2001	F.C. Thomas Allnutt	031676.0247	7694

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EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,093	ALLNUTT ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2-3-04.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 15-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 15-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant response to the office action mailed November 04, 2003 has been acknowledged. Currently, claims 15-19 are pending and under consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al (USP#6,232,107).

Bryan et al discloses fusion proteins that consist of a nucleic acid, particularly a DNA encoding luciferase with a DNA encoding a GFP or phycobiliproteins (column 7, lines 19-35). The expressed fusion protein has two domains, a phycobiliprotein and a luciferase as required by claim 15. The fusion protein can be used in analytical applications, such as cell based assays and screening methods (column 7, lines 25-35). Other assay systems include homogenous immunoassays and in vitro fluorescent-based screening (column 6, lines 30-40). The interaction of the second domain that is a luciferase enzyme in the presence of a luciferin molecule and appropriate binding

factors, that can be a variety of particular entities, can undergo a known biologic effect such as an bioluminescence (column 7, lines 15-31).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al (USP#6,232,107).

The teachings of Bryan et al are set forth above and is different with respect to teaching a particular enzymes.

However, Bryan et al teaches fusion proteins and utilizing luciferase as a second domain that is able to catalyze substrates to produce a detectable change (column 31, lines 65-66 and column 32, lines 1-10).

It would have been obvious to one of ordinary skill in art to modify the reference of Bryan et al to include using known enzymes such as a ribozyme, phosphokinase or a protease in the various assay methods and detection systems taught by the instant reference. These modifications with respect to the particular enzyme employed are routine optimizations that are almost always varied and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected

difference over the prior art, it would have been ***prima facie*** obvious for one of ordinary skill in the art to substitute the known enzymes of claims 17-19 in the given assay parameters to assess biological activity as a means of optimizing the assays provided by the art.

Response to Arguments

6. Applicant's arguments filed February 3, 2004 have been fully considered but they are not persuasive:

7. Applicant argue that the reference of Bryan et al does not anticipate the instant invention because Luciferase assays are well known in the art to have some very specific and well known features and are broadly represented of biologically assays. Also GFP is a much simpler fluorescent protein than phycobiliprotein. The only references to phycobiliprotein are very generalized comments, which provide no treaching for phycobiliproteins in a fusion protein.

In response to applicant's argument, the reference of Bryan et al teaches a fusion protein having a phycobiliprotien and a luciferase enzyme as a second domain. When the fusion protein is in the presence of luciferin, it undergo a known biologic effect such as bioluminescence (column 7, lines 15-31) as recited in the instant claims. The teachings of Luciferase assays are not inhibited by the instant claims. Also, the reference of Bryan et al teaches fusion proteins that known to be GFPs or phycobiliproteins. Therefore, the reference of Bryan et al anticipates claim 15.

8. Applicant argues that claim 16 calls for an enzyme as a second domain in the fusion protein, and that enzymes would not be changes by an encounter.

This argument is found persuasive because the reference of Bryan et al does not teach that the second domain serves as a substrate for an enzyme. The reference of Bryan et al teaches that the second domain in the fusion protein is luciferase, which is an enzyme. Therefore, applicant has overcome the rejection of claim 16.

9. Applicant argues that the reference Bryan et al does not cite that its fusion protein is an improvement. This argument is not found persuasive.

In response to applicant's argument, the fact that Bryan et al discloses a fusion protein comprising a phycobiliprotein and a second domain used for detectable tags, is the improvement recited in the instant claims (column 85, lines 33-47).

10. Applicant argues that the second domain of the instant fusion protein in claim 15 and its dependent claims 16-19 is not an enzyme.

This argument is not found persuasive because independent claim 15 does not recite that its second domain is not an enzyme, only its independent claims. Dependent claims 17-19 depend from claim 15. Therefore, it is the examiner's position that the reference of Bryan et al meets these limitations.

Allowable Subject Matter

11. Claim 16 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

Conclusion

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis
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April 30, 2004

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05/03/04